

**COOLRAIL LINEAR PEN 510(k) SUMMARY****MAR 11 2008****General Information**

Classification	Class II
Trade Name	Coolrail linear pen
Manufacturer	AtriCure, Inc 6033 Schumacher Park Dr West Chester, OH 45069
Contact	Alison M. Grimaldi Clinical & Regulatory Engineer II

**Indications for Use**

The Coolrail™ Linear Pen (Coolrail Pen) is a sterile, single use electrosurgery device intended to ablate cardiac tissue during cardiac surgery using radiofrequency energy.

**Predicate Devices**

The predicate devices for the Coolrail Linear Pen are the AtriCure Isolator Transpolar Pen (K050459), the Medtronic Cardioblate Monopolar Pen (K013392), and the Boston Scientific Flex 4 Ablation Probe (K003978).

**Device Description**

The Coolrail Linear Pen is a sterile, single use, electrosurgery device to be used in conjunction with an electrosurgical generator for the delivery of radiofrequency current.

**Materials**

All materials used in the manufacture of the Coolrail Linear Pen are suitable for this use and have been used in numerous previously cleared products. Testing was conducted in accordance with ISO 10993-1 to ensure appropriate biocompatibility of all materials.

**Testing**

Appropriate product testing was conducted to evaluate conformance to product specification and substantial equivalence to predicate devices.

**Summary of Substantial Equivalence**

The Coolrail Linear Pen is equivalent to the predicate products. The indications for use, basic overall function, and materials used are substantially equivalent.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

MAR 11 2008

Atricure, Inc.  
c/o Mr. Mark Job  
Director, Quality and Regulatory Systems  
Regulatory Technology Services, LLC  
1394 25<sup>th</sup> Street, NW  
Buffalo, MN 55313

Re: K073605  
Atricure Coolrail Linear Pen  
Regulation Number: 21 CFR 878.4400  
Regulation Name: Electrosurgical cutting and coagulation device and accessories  
Regulatory Class: Class II (two)  
Product Code: OCL  
Dated: December 20, 2007  
Received: December 21, 2007

Dear Mr. Job:

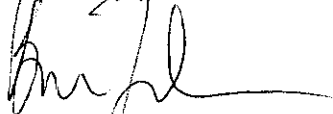
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Bram D. Zuckerman, M.D.  
Director  
Division of Cardiovascular Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known) \_\_\_\_\_

Device Name: Coolrail Linear Pen

Indications for Use:

*The Coolrail™ Linear Pen is a sterile, single use electosurgery device intended to ablate cardiac tissue during cardiac surgery using radiofrequency energy.*

Prescription Use   X    
(Part 21 CFR 801 Subpart D)

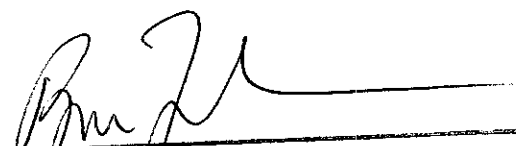
AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
\_\_\_\_\_  
(Division Sign-Off)  
Division of Cardiovascular Devices  
510(k) Number   K073605